AMENDMENTS TO THE SPECIFICATION

In the paragraph commencing on page 1, line 21; please amend as reflected in the following marked-up version of the paragraph:

In order to perform many vascular procedures a guidewire is initially inserted into the patient's vasculature. The guidewire is generally inserted into the patient through an incision created in the patient's femoral artery. After the guidewire has been placed within the patient's vasculature, other interventional devices, such as catheters, maybe be passed over the guidewire. As used herein, the term "interventional device" is intended to include, but not be limited to, any known devices capable of being inserted within the human vasculature for diagnosis, treatment or inspection thereof. Additionally the terms "catheter" and "guidewire" as utilized herein are intended to be interchangeable when referring to the medical device in accordance with the present invention.

In the paragraph commencing on page 5, line 22; please amend as reflected in the following marked-up version of the paragraph:

A further object of the present invention is to provide ~~a n~~ medical device wherein ~~a n~~ balloon disposed upon the distal end portion of the device may be selectively inflated or deflated through a valve means wherein the inflation device is removable from the valve means.

In the paragraph commencing on page 9, line 6; please amend as reflected in the following

marked-up version of the paragraph:

Figure 1 is a side view of the ~~-~~medical device according to the present invention;

In the paragraph commencing on page 9, line 17; please amend as reflected in the following marked-up version of the paragraph:

Figure 4~~,~~ is a partial cross-sectional side view of another representative embodiment of the distal tip of the ~~-~~medical device according to the present invention;

In the paragraph commencing on page 19, line 1; please amend as reflected in the following marked-up version of the paragraph:

Referring now to Figure 2 there is shown a partial cross-sectional side view of the distal end portion 102 of the medical device 100. As shown in Figure 2, a flexible tip 160 may extend from the distal end portion 102 of the elongated body 105. A variety of distal tip configurations are known and used in the art, each generally capable of performing particular functions. For example, and as embodied herein, the flexible tip 160 is constructed of a solid inner core wire 162 of type 304 stainless steel, wherein the solid core 162 is wrapped with a bio-compatible wire 164. Examples of a bio-compatible wire 164 which may be utilized include stainless steel, Nitinol, Titanium, Platinum, Iridium, and similar bio-compatible materials. In a preferred embodiment the bio-compatible wire

164 is a platinum wire. Platinum wire is preferably used because platinum wire is visible under fluoroscopy thereby enabling a surgeon to locate the flexible tip 160 within a patient's body in use. The pre-formed curve 169, in addition to a blunt tip 167 form, ~~an~~includes an-atramatic tip thereby allowing the medical device 100 to be inserted within a patient's vasculature. The pre-formed curve 169 ensures that the blunt tip 167 does not pierce the vessel/artery or organ through which the medical device 100 is being advanced. It shall be understood that the pre-formed curve 169 remains sufficiently pliable and elastic whereby an interventional device may be advanced over the outer diameter of the medical device 100 such that the pre-formed curve 169 will straighten and all the medical device to pass over. Such tip designs are well known in the art.

In the paragraph commencing on page 28, line 21; please amend as reflected in the following marked-up version of the paragraph:

Referring now to Figure 9, there is shown a preferred embodiment of the valve body 150 in accordance with one aspect of the present invention. The valve body 150 includes a proximal end portion 154 and a distal end portion 152, and a cavity/or lumen 151 ~~156~~ formed there between. The distal end portion 152 of the valve body is adapted to sealingly engage the outer diameter of the elongated body shown in Figure 11.

In the paragraph commencing on page 29, line 6; please amend as reflected in the following marked-up version of the paragraph:

The cavity 156 of the valve body 150 may further include a pliable coating to aid in the sealing of the valve body to the elongated body 105. The coating may be silicone, urethane, TFE. In a preferred embodiment the pliable coating is a parylene coating. The valve body 150 may be constructed of a bio-compatible material such as titanium, stainless steel, polyurethane, polyvinyl chloride, Nitinol, or similar materials, wherein the cavity 151 of valve body ~~further~~ is ~~has a~~ closed at proximal end portion ~~154~~ 154 by way of ~~such as~~ a plus 158 disposed within the cavity or lumen 151 of the valve body 150.

In the paragraph commencing on page 30, line 12; please amend as reflected in the following marked-up version of the paragraph

In accordance with the present invention, referring now to Figures 6, 9, and 11 there are shown partial cross-sectional side views of a first representative embodiment of the medical device 100. The proximal end portion 104 of the medical device 100 is shown in Figures 6, 9, and 11. Figures 9 and 11 illustrate a first representative embodiment of the valve body 150, wherein as shown in Figure 11, the valve body 150 can be disposed about the proximal end portion 104 of the elongated body 105. The valve body 150 includes an elongated body having a proximal end portion 154 and a distal end portion 152, wherein the distal end portion 152 is adapted to sealingly receive the elongated body 105 of the medical device 100, and the proximal end portion has a ~~closed or blind end~~ plug 158 to close the proximate end of the value body 150. As embodied herein, the valve body

150 therefore is moved axially between an open position and a closed position as described in greater detail below.

In the paragraph commencing on page 31, line 22; please amend as reflected in the following marked-up version of the paragraph

The valve body 150 defines a cavity or lumen 151 therein to receive the outer diameter of the elongated body 105. If cylindrical in shape, the valve body may have an inner diameter between about .10 millimeters and about 2.0 millimeters, preferably between about 0.25 millimeters and about 1.0 millimeters and most preferably between about 0.300 millimeters and about 0.500 millimeters. The valve body further has a wall thickness between about .001 millimeters and about .10 millimeters, preferably between about 0.025 millimeters and about .05 millimeters, most preferably between about .03 millimeters and about .04 millimeters.

In the paragraph commencing on page 33, line 12; please amend as reflected in the following marked-up version of the paragraph

If desired, the proximal end portion 104 of the elongated body 105 may have a closed or blind end, such as by providing a plug 103 disposed to seal the lumen 101 as shown in Figure 6. The plug may be constructed of a bio-compatible material such as titanium, stainless steel, Nitinol, delrin, nylon, or similar materials. The plug 103 embodied herein is affixed within the lumen 101 of the

elongated body with a bio-compatible adhesive which will adhere to the plug 103 and the inner wall of the lumen 101. In a preferred embodiment, the plug 103 is formed of solder such as that described above with regard to the valve body 150 of Figure 9. Alternatively, the plug 103 is not necessary because the distal end 152 of the valve body 150 sealingly contacts the outer diameter of the elongated body 105 thereby creating hemostasis within the medical device 100. It shall be understood that if the plug 103 is not disposed within the lumen 101 of the elongated body 105, the valve body 150 must include the plug 158 in order to form a fluid tight seal within the elongated body 105.

In the paragraph commencing on page 34, line 9; please amend as reflected in the following marked-up version of the paragraph

Referring now to FIGS. 11 and 12 there is shown the medical device 100 in accordance with one aspect of the present invention in use. As shown in FIG. 11, the valve body 150 is disposed upon the proximal end portion 104 of the elongated body 105, wherein the valve body is in a closed position. The distal end 152 of the valve body forms a fluid tight seal with the step 117 of the elongated body 105. The fluid tight seal may be formed through an interference fit between the distal tip 152 of the valve body and the step 117 or altertnatively, as described herein the inner diameter of the valve body may include a parylene coating for enhanced sealing properties. Referring now to FIG. 12 there is shown the valve body 150 in an open configuration. Wherein, when the valve body 150 is in an open configuration having been moved a distance away from the step 117 as denoted by

the reference number 90, inflation fluid may be introduced into the lumen 101 of the elongated body 105 thereby inflating the balloon 120 of the distal tip portion 102. Inflation fluid may be introduced in a manner such as that disclosed by Teitlebaum, U.S. Pat. No. 5,807,330. Alternatively, inflation fluid may be withdrawn from the lumen 101, thereby deflating the balloon 120. As shown in FIGS. 11 and 12, the valve body 150 may be selectively opened and closed in order to control the inflation and deflation of the balloon 120. To move the valve body between an opened and closed position as shown an axial force or a radial force or a combination thereof may be applied to either or both the valve body 150 or the elongated body 105. Additionally, the valve body 150 only need be moved between about 0.005 inches and about 1.0 inches, preferably between about 0.02 inches and about 0.75 inches, most preferably between about 0.05 inches and about 0.25 inches.

In the paragraph commencing on page 35, line 19; please amend as reflected in the following marked-up version of the paragraph

Another alternative embodiment in accordance with the present invention is illustrated in Figure 33, wherein there is shown a medical device 100 having a valve body 150 disposed upon the proximal end portion 104 of the elongated body, wherein the plug 158' of the valve body forms a fluid tight seal with the very proximal end 137 of the elongated body 105. The plug 158' may further include a pliable coating as those described above in order to effectuate a better seal with the proximal end 137 of the elongated body 105. Furthermore, frictional interference between the ~~chamber~~ cavity or lumen 151~~156~~ of the valve body and the outer diameter of the elongated body 150

act to retain the valve body 150 upon the proximal end portion 104 of the elongated body 105. It shall be understood that the medical device 100 embodied and described with reference to Figure 33 may be adapted to include any other feature described herein in relation to other embodiments of the medical device 100.

In the paragraph commencing on page 37, line 8; please amend as reflected in the following marked-up version of the paragraph

As shown in Figures 13 and 14, there second step 118 can provide improved inflation and deflation of the balloon when the valve sleeve 150 is moved proximally into an opened position. This is because, as the valve body is moved from a closed position to an opened position, the valve body 150 does not have to be moved past the openings 113 formed in the wall of the elongated body 105. That is, once the distal end 152 of the valve body 150 passes proximal the second step 118 as shown in Figure 14, a fluid flow path is formed between the second reduced diameter portion and the cavity or lumen 151 of the valve body 150. Indeed, by providing such a flow path, the extreme proximal end of the elongated body as shown in Figures 13 and 14, can be used to define an opening for inflation of the balloon such that additional openings need not be provided in the wall of the elongated body 105.

In the paragraph commencing on page 38, line 3; please amend as reflected in the following marked-up version of the paragraph

Referring now to Figures 8 and 15 there is shown yet another alternative embodiment of the proximal end portion 104 of the medical device 100 in accordance with the present invention. As shown in Figures 8 and 15, the proximal end portion 104 of the medical device 100 may include tapered section 515, which can be formed by known techniques, such as grinding, milling, EDM, laser cutting or swagging. The embodiment herein defines a constant angle of between about 0 and about 45 degrees, more preferably between about .5 and about 3 degrees. As shown in Figure 15 a valve body 150 is disposed about the tapered section 515, wherein the distal end 152 of the valve body contacts the outer surface of the elongated body 105 thereby sealing the openings 113 when in a closed position. The valve body 150 may be moved axially, whereby an annular space is created about the distal ed 152 of the valve body 150 and the tapering outer diameter of the elongated body 105, thereby allowing for fluid to flow from the annular space into the lumen 101 and the chamber 123 Figure 4 of the balloon.

In the paragraph commencing on page 39, line 1; please amend as reflected in the following marked-up version of the paragraph

In accordance with the present invention an opening is provided at the proximal end portion 104 of the elongated body 105, the opening being in fluid communication with the balloon 120 via the lumen 101 of the elongated body 105, wherein the opening may be embodied in a variety of configurations. As previously noted, the opening may be defined as the extreme proximal end of the

elongated body. Alternatively, and as embodied herein, the opening may include at least one opening 113 disposed through the wall of the elongated body 105 at the proximal end portion 104 thereof. Preferably, and when the proximal end portion 104 is provided with an area of reduced cross-section, the opening is located within the reduced diameter area 115 or 515 of the proximal end portion 104 of the elongated body 105.

In the paragraph commencing on page 41, line 14; please amend as reflected in the following marked-up version of the paragraph

Referring now to Figure 24, the elongated body 105 and the valve body 450 includes each of the elements described above and illustrated in Figure 11. Additionally, the elongated body 105 includes a slot 413 formed within the wall of the elongated body 105 wherein the slot 413 may be formed partially into the outer wall, such as by a groove or dimple, or extend entirely through the wall of the elongated body 105 as an opening. The valve body 450 is disposed about the proximal end portion 104 of the elongated body 105 in the manner as described above. The valve body 450 may further include a protrusion 455 extending into the cavity ~~456~~ 451 of the valve body. The protrusion 455 is slidably received within the slot 413 of the elongated body 105. The protrusion 455 therefore may retain the valve body 450 upon the proximal end 104 of the elongated body 105, and limit the proximal movement of the valve body. The protrusion 455 also may further provide tactile feedback to a user indicating whether the valve body is in an opened or closed configuration. The protrusion may be formed as a separate body attached to the valve body 450, or the protrusion

may be formed integral with the valve body 450. Alternatively, the reduced diameter section may include a protrusion, either integrally formed therewith or fixedly attached thereto and the valve body may include a slot or groove adapted to receive the protrusion of the reduced diameter section.

In the paragraph commencing on page 42, line 20, please amend as reflected in the following marked-up version of the paragraph

Referring now to Figures 20-22, there is shown an alternative embodiment of the valve body 550 and reduced diameter portion 515. The reduced diameter portion 515 further includes a groove 519, formed in the wall of the elongated body 105. The groove 519 may be formed in the wall of the elongated body by machining, grinding, EDM milling, or similar manufacturing processes. Alternatively, the groove 519 may be formed by deforming the wall of the elongated body as shown in Figure 30. The valve body 550 includes a pin 555 or similar protrusion extending into the cavity ~~556~~551. When the valve body 550 is disposed about the reduce diameter portion 515, the pin 555 is received within the groove 519, wherein the groove 519 guides the pin 555 during translation of the valve body 550 between an opened position and a closed position. The groove 519 may be axially aligned with the lumen 101 of the elongated body 105 as shown in Figures 20-22, or extend helically to induce rotational movement of the valve body during displacement. Alternatively, the groove 519' may be both axially and radically aligned with the lumen 101 of the elongated body 105 as shown in Figure 23. By having a groove 519' that is both axially and radially aligned requires that the valve body 550 be rotationally translated first and then axially translated in order to open the seal

between the valve body and the elongated body. This greatly reduces or eliminates the possibility of the valve body 550 from being accidentally opened.

In the paragraph commencing on page 45, line 22; please amend as reflected in the following marked-up version of the paragraph

Referring now to Figures 28-32, there is shown an additional alternative embodiment in accordance with the present invention. Referring to Figure 28 there is shown partial cross-sectional top view of a medical device 800, wherein the medical device 800 includes an elongated body 805 having a distal portion (not shown) and a proximal end portion 804, wherein the proximal end portion 804 includes at least one groove 830 formed therein as shown in Figure 30. The medical device 800 further includes an opening 815 disposed adjacent to the proximal end portion 804 of the elongated body 805. As shown in Figure 29, the opening 815 may be formed as a skive. Although the opening 815 is shown to be embodied as a skive this should not be considered limiting in any manner, it is contemplated that any of the openings described herein may be utilized in addition to or as an alternative to the skive. The skive 815 may be formed utilizing any of the methods described above.